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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,907	07/25/2003	Mark Van Dyke	SwRI-2966-03	2421

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EXAMINER	
BRADRICK, THOMAS DALE	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,907	VAN DYKE ET AL.	
	Examiner	Art Unit	
	Thomas D. Bradrick	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-220* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-220* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, drawn to a medical device comprising a substrate comprising a passivating coating comprising keratin, the passivating coating being effective to increase bone matrix formation exhibited by cultured 2T3 mouse osteoblast cells, classified in class 424, subclass 422.

II. Claims 79-102, drawn to a medical implant comprising (a) a substrate comprising a metal, alloy or ceramic substrate, and (b) a passivating coating comprising HMWK keratin and bone morphogenic protein (BMP) and/or transforming growth factor beta (TGF-β) and being effective to increase bone matrix formation exhibited by cultured 2T3 mouse osteoblast cells, a bonding region and a bioactive region, classified in class 424, subclass 426.

III. Claims 34-78 and 161-220, drawn to a medical implant comprising a substrate comprising a passivating coating comprising (a) keratin, (b) a bonding region and (c) a bioactive region, the bonding region comprising at least one organosilane compound comprising a silane component bound to a surface of the substrate, and the bioactive region comprising an organic component of the organosilane bound to a reactive pendant group on the keratin, classified in class 424, subclass 426.

IV. Claims 103-160, drawn to a method of coating a medical device with a passivating coating, the method comprising (a) bonding a coupling agent to one or more surfaces of the medical device, producing a bonding region, and (b) bonding keratin to the bonding region, classified in class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. Keratin could be incorporated into the passivating coating itself, which could be applied to the substrate.

Inventions I, II and III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products are mutually exclusive, are not obvious variants, and have a materially different design as they are drawn to medical devices or implants having different arrangements and inter-relationships of substrates and coatings.

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference that would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple products that have distinct compositions. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: biocompatible materials selected from the group consisting of metals, metal alloys, and ceramics (specifically titanium, hydroxyapatite and silicon compositions; bioactive factors selected from the group consisting of BMP and TGF-β; sources of keratin selected from the group consisting of hair, fur, feathers, horns, hooves, beaks and feet; organosilane moieties selected from the group consisting of epoxy, alkoxy, vinyl, amine, isocyanate and carboxyl groups; anhydrous solvents selected from the group consisting of methanol, ethanol, isopropyl alcohol, dimethylsulfoxide, acetone, tetrahydrofuran and dichloromethane; and bases selected from the group consisting of

ammonium hydroxide, sodium hydroxide and potassium hydroxide. The species are independent or distinct because they comprise different compounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5-12, 38-43, 45-47, 49-51, 53-55, 57, 79, 80, 81, 83, 90-93, 95, 108, 109, 111, 112, 122 –137, 165, 166, 168-170, 172-174, 176, 200-216 and 218-220 are generic.

If electing Group I, please elect a single species from claim 5, namely metals, metal alloys or ceramics, and a single species from claim 6, namely titanium or hydroxyapatite and consistent with the election of claim 5; a single species from claims 7-9, namely BMP or TGF-β; and a single species from claims 10-12, namely hair, fur, feathers, horns, hooves, beaks or feet.

If electing Group II, please elect a single species from claims 79 and 91, namely BMP or TGF-β; a single species from claims 80 and 92, namely epoxy, alkoxy, vinyl, amine, isocyanate or carboxyl groups; and a single species from claim 90, namely titanium or hydroxyapatite. Please note that because claims 81, 83, 93 and 95 are drawn to the same or similar limitations as claims 80 and 92, but the species claims of the former constitute subsets of those of the latter, an election from the latter will also constitute an election from the former (*i.e.*, claims 81, 83, 93 and 95 will not be searched separately from claims 80 and 92).

If electing Group III, please elect a single species from claims 38-41, namely BMP or TGF-β; a single species from claims 42, 46, 50, 54, 165, 169 and 173, namely

epoxy, alkoxy, vinyl, amine, isocyanate or carboxyl groups; a single species from claims 200, 203, 206, 209, 212, 215 and 218, namely metals, metal alloys or ceramics, and a single species from claim 201, 202, 204, 205, 207, 208, 210, 211, 213, 214, 216, 219 and 220, namely titanium, hydroxyapatite or silicon compositions and consistent with the elections of claims 200, 203, 206, 209, 212, 215 and 218. Please note that because claims 43, 45, 47, 49, 51, 53, 55, 57, 166, 168, 170, 172, 174 and 176 are drawn to the same or similar limitations as claims 42, 46, 50, 54, 165, 169, 173 and 174, but the species claims of the former constitute subsets of those of the latter, an election from the latter will also constitute an election from the former (*i.e.*, claims 43, 45, 47, 49, 51, 53, 55, 57, 166, 168, 170, 172, 174 and 176 will not be searched separately from claims 42, 46, 50, 54, 165, 169, 173 and 174).

If electing Group IV, please elect a single species from claims 108, 109, 111 and 112, namely methanol, ethanol, isopropyl alcohol, dimethylsulfoxide, acetone, tetrahydrofuran and dichloromethane; a single species from claims 122 and 123, namely ammonium hydroxide, sodium hydroxide or potassium hydroxide; and a single species from claims 124-137, namely methanol, ethanol, isopropyl alcohol, dimethylsulfoxide, acetone or tetrahydrofuran.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final

rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is 571-272-

8139. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached at 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas Bradrick
Patent Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER